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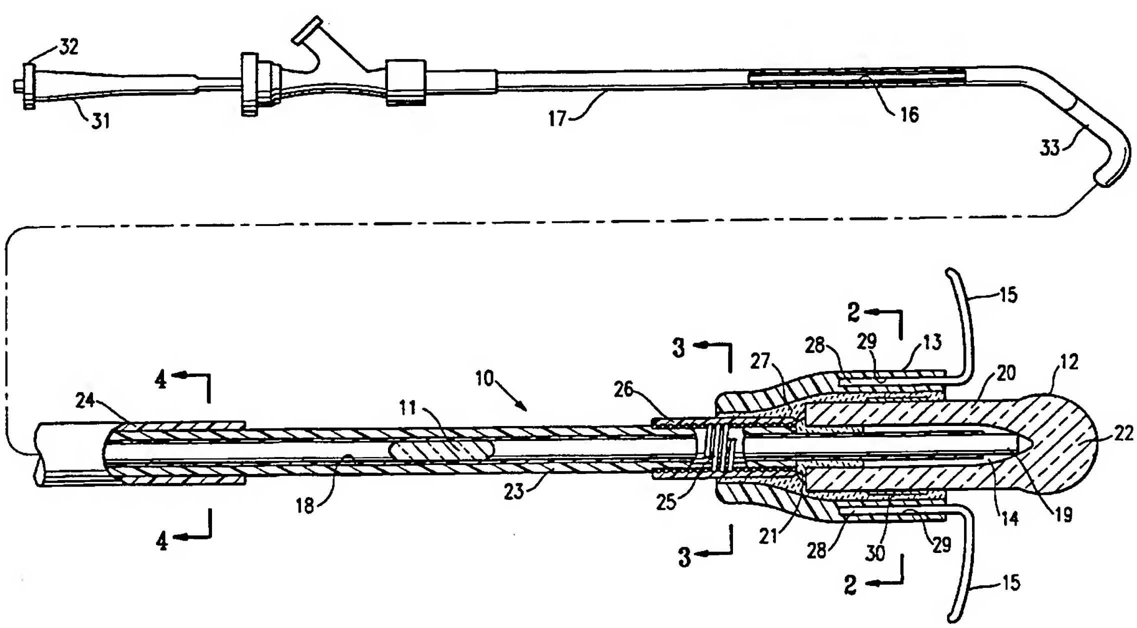

(57) Abstract

A laser device for forming channels within an outer wall of a patient's heart which has an elongated optical fiber, a lens or probe tip secured to the distal end of the optical fiber and means to limit the penetration of the probe tip or lens. Preferably, an outer support sleeve is secured to the proximal portion of the probe tip and a distal portion of the optical fiber proximal to the probe tip. In one preferred embodiment of the invention, a helical coil is disposed between the distal portion of the optical fiber and the proximal portion of the probe tip to ensure a better bond therebetween, particularly when the optical fiber has a lubricous fluoropolymer coating.

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SURGICAL CHANNEL FORMING DEVICE WITH PENETRATION LIMITER

RELATED APPLICATIONS

This application is a continuation-in-part of copending application Serial No. 08/482,125, filed on June 7, 1995, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

This invention is directed to the formation of one or more channels into the wall of a patient's heart which may be used to increase blood flow to heart tissue experiencing ischemic conditions, for the delivery of therapeutic or diagnostic agents to various locations in the patient's heart or for a variety of other utilities.

The formation of a channel in a patient's ventricular wall to increase the blood to flow to a patient's heart tissue is called trans myocardial revascularization. The first clinical trials of the trans myocardial revascularization process were performed by Mirhoseini *et al.* See for example the discussions in Lasers in General Surgery (Williams & Wilkins; 1989), pp 216-223. Other early disclosures of this procedure is found in an article by Okada *et al.* in Kobe J. Med. Sci 32, 151-161, October 1986 and U.S. Patent 4,658,817 (Hardy). These early

references describe intraoperative revascularization procedures which require an opening in the chest wall and include formation of the channels through the epicardium.

Copending application Serial No. 08/361,787, filed December 20, 1994 (Aita *et al.*), which is incorporated herein in its entirety, describes a system for trans myocardial revascularization which is introduced through the chest wall. In U.S. Patent No. 5,389,096 (Aita *et al.*) a percutaneous method is described for forming a channel in a patient's ventricular wall wherein an optical fiber device is advanced through a peripheral artery such as the femoral artery, through the aorta into the patient's left ventricle. Within the left ventricle, the distal end of the optical fiber device is directed toward a desired location on the patient's endocardium and urged against the endocardial surface while a laser beam is emitted from its distal end to form the channel. The depth of penetration of the distal end of the laser device is affected by the force applied by the distal end to the tissue into which the channel is being formed. Because of the nature of the environment, i.e. fluid currents, the moving heart surface and the uneven surface of the patient's endocardium, controlling the force applied to the endocardial tissue by the end of the laser device can be quite difficult. Complete penetration through the ventricular wall from within the ventricular chamber is not desirable.

The present invention minimizes the difficulties with these prior channel forming devices.

SUMMARY OF THE INVENTION

The present invention is directed to an improved device for forming a channel in a ventricular wall of a patient's heart and particularly in the free-wall defining in part the left ventricle of the patient's heart.

The channel forming device of the invention generally includes an elongated shaft with a proximal and distal shaft sections. A means to form a channel in the ventricular wall of the is provided on the distal shaft section and a means to limit the depth of penetration of the distal shaft section into heart tissue during the formation of the channel therein. The means to limit the depth of penetration is preferably at least one radial projection on the distal shaft section spaced proximally from the means to form the channel on the distal shaft section.

In one presently preferred embodiment, the invention includes an elongated optical fiber having a proximal end and a distal end and a distal probe tip secured to the distal extremity of the optical fiber. The laser device is provided with one or more radially extending projections spaced from the distal end of the device which acts as a stop to limit the penetration or forward motion of the operative end of the device into the ventricular wall during channel formation, which in turns controls the depth of the channel into the ventricular wall. The means to limit the penetration into the ventricular wall may be a plurality of arms, preferably four, which fold back when the channel forming device is advanced within a guiding or delivery catheter to the ventricular chamber, but which expand outwardly when the distal section exits the distal end of the guiding or delivery catheter within the chamber. Another means for limiting the depth of penetration into the ventricular wall is to provide a radially projecting shoulder on the exterior of the distal shaft section proximal to the channel forming means. In each of these means the stopping surface is spaced from the distal end of the probe tip the desired penetration distance for the distal tip of the device. By providing the means to control the depth of penetration, there is no need for concern about the pressure applied by the physician to the channel forming device affecting the depth of penetration which may

lead to the complete penetration of the ventricular wall. A wide variety of means can be used to prevent such penetration.

The presently preferred channel forming device is an elongated optical fiber with a distal probe tip on the distal end of the optical fiber to control the emission laser radiation therefrom. The distal probe tip preferably has an interior chamber into which the distal extremity of the optical fiber extends and an outer support member or sleeve is secured to the proximal portion of the probe tip and a distal portion of the optical fiber extending out the proximal end of the probe tip to ensure the integrity of the probe tip and optical fiber during the channel forming procedure. The outer support sleeve may be shrunk fit onto the probe tip or it may be bonded by a suitable adhesive. Further details of this construction can be found in copending application Serial No. 08/482,125, filed on June 7 1995.

In a presently preferred device for forming channels in the ventricular wall from within the ventricular chamber which is percutaneously introduced into the patient's vascular system, the probe tip length is about 3 to about 20 mm and the length of the portion of the probe tip which extends out the distal end of the outer support member is about 1 to about 5 mm. Generally, at least about 1 mm of the proximal portion of the probe tip, preferably at least about 2 mm thereof, is secured by the outer support member to ensure holding the probe tip in the case of a fractured probe tip. The proximal portion of the outer support member secured to the distal end of the optical fiber should be at least about the same length as described above for the distal portion, although generally it will be longer. For an interoperative device which is designed to form channels from the exterior of the patient's heart the dimensions may be significantly larger than those set forth above for a percutaneous device.

An adapter is provided on the proximal end of the device which is configured to connect the proximal end of the optical fiber in an optical transmission relationship with a laser source.

While forming a passageway through the wall of the patient's heart for the purpose of revascularization is of significant importance, the passageway formed into the heart wall may be used for other purposes. For example, therapeutic or diagnostic agents may be introduced into the channel for delivery to the patient's endocardium or myocardium. The therapeutic or diagnostic agent may be incorporated into a biocompatible matrix deposited within the channel for delivery or release over an extended period.

These and other advantages of the invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view, partially in section, of a channel forming device embodying features of the present invention.

Fig. 2 is a transverse cross-sectional view of the channel forming device shown in Fig. 1, taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the channel forming device shown in Fig. 1, taken along the lines 3-3.

Fig. 4 is a transverse cross-sectional view of the channel forming device shown in Fig. 1, taken along the lines 4-4.

Fig. 5 is an end view of the device shown in Fig. 1.

Fig. 6 is an elevational view of the device shown in Fig. 1 disposed within a guiding catheter.

Fig. 7 is an elevational view, partially in section, of the device shown in Fig. positioned adjacent to a patient's heart wall with the laser probe tip disposed within the formed channel.

Fig. 8 is an elevational view, partially in section, of an alternative channel forming device embodying features of the present invention.

Fig. 9 is a transverse cross-sectional view of the channel forming device shown in Fig. 7, taken along the lines 8-8.

Fig. 10 is a transverse cross-sectional view of the channel forming device shown in Fig. 7, taken along the lines 9-9.

Fig. 11 is a transverse cross-sectional view of the channel forming device shown in Fig. 7, taken along the lines 10-10.

DETAILED DESCRIPTION OF THE INVENTION

In Figs. 1 - 4 a channel forming device 10 is shown which embodies features of the invention. The device 10 includes an elongated optical fiber 11, an elongated probe tip 12 disposed about and secured to the distal extremity of the optical fiber, and an outer tubular support member or sleeve 13 secured to the exterior of the proximal extremity of the probe 12 and a distal portion of the optical fiber which is not disposed in the interior chamber 14 of the probe 12. A plurality of radially extending arms 15 are provided proximal to the distal end of the probe tip to limit the penetration of the probe tip into the patient's ventricular wall. The channel forming device 10 is slidably disposed within the inner lumen 16 of guiding catheter 17. A positioning catheter (not shown) may be disposed between channel forming device 10 and the guiding catheter 17 which can facilitate closer placement of the probe tip 12 onto the endocardium of the ventricular wall as described in copending application Serial No. 08/438,743, filed on May 10, 1995. This latter application is incorporated herein in its entirety by reference.

The exterior of the optical fiber 11 is provided with a fluoropolymeric cladding 18 along its length except for a distal portion

19 which extends into the distal end of the interior chamber 14 of the probe tip 12.

The elongated probe tip 12 has a cylindrical body 20 which is bonded to the distal end of the optical fiber 11 by adhesive 21. The probe tip 12 has a distal end 22 which acts as a lens to control laser energy emitted from the distal end of the optical fiber to a location immediately distal to the lens to ensure formation a channel of a desired size in the ventricular wall. A fluoropolymer buffer 23 is disposed about the optical fiber 11 proximal to the body of adhesive 21 and extends proximally along essentially the remainder of the optical fiber. An outer jacket 24 is disposed about the fluoropolymer buffer 23 along most of its length, and terminates about 10 cm from the proximal end of the outer tubular support member 13. A helical coil 25 formed of high strength material such as stainless steel, NITINOL and the like is disposed between the fluoropolymer buffer 23 and the proximal end of the outer tubular support member 13 and has a jacket 26 formed of suitable plastic material such al polyethylene terephthalate (PET). The coil 25 and jacket 26 together facilitate an effective bond between the fluoropolymer buffer 23 and the outer tubular support member 13. Adhesive 27 bonds the outer tubular support member 13 to the coil jacket 26.

The radially extending arms 15 are U-shaped flexible wire members with the free ends 28 embedded within the outer tubular support member 13. Preferably, the outer tubular support member 13 is provided with lumens 29 which receive the free ends 26 of the arms 15 and are secured therein by a suitable adhesive (not shown). Other means may be utilized to secure the free ends 28 of the arms 15 between the probe tip 12 and the exterior of the outer tubular support member 13. When expanded radially, the arms 15 act to limit the penetration of the probe tip 12 into the channel as it is being formed in

the ventricular wall and thus controls the depth of the channel formed. As is shown in Fig. 6, the arms 15 are folded backwardly while the probe tip 12 of optical fiber device 10 is disposed within the inner lumen 16 of the guiding catheter 17. Alternatively, they may be folded forwardly as shown in phantom in Fig. 6. Preferably, the arms 15 are formed of a NiTi alloy having superelastic characteristics at body temperature to facilitate the folding thereof within the guiding catheter 17 and the radial expansion thereof once the probe tip 12 extends out of the distal end of the guiding catheter. Folding the arms 15 causes the stress induced transformation of the austenite phase of the NiTi alloy in the bent portions to the martensite phase and release of the arms to allow for their radial expansion causes the transformation of the martensite phase back to the austenite phase.

A radiopaque band 30 may be secured to the exterior of the cylindrical body 20 by the adhesive 27 to facilitate the fluoroscopic observation of the probe tip 12 during the procedure. The band may be formed of a wide variety of metallic components including gold, platinum iridium and the like.

The proximal end of the device 10 is provided with a connector 31 which has a rotatable, internally threaded collar 32 which facilitates an optical connection of the proximal end of the optical fiber 11 with a source of laser energy.

The distal end 33 of the guiding catheter 17 is preferably formed into a desired shape which directs the distal extremity of the optical fiber 11 and the probe tip 12 onto a desired location on the surface of the free ventricular wall of the patient's heart. If a positioning catheter is employed, its distal end may likewise be formed with a desirable shape to facilitate directing the probe tip to the desired location.

The various components of the device 10 may be formed of a wide variety of conventional materials used in the construction of intravascular catheters and other intracorporeal devices. The contemplated materials of construction and the sources thereof for one presently preferred embodiment are provided in the following table.

COMPONENT	MATERIAL	SUPPLIER
Proximal Optical Connector	Various	Amphenol Corporation Lisle, IL and Spectran[1] Specialty Optics, Co. Avon, CT
Jacket (24)	Pebax 7233 tubing with 3% TiO_2	North American Infinity Extrusions and Engineering, Inc. Santa Clara, CA 95054
Tubular Support Member (13)	Nylon 12, 1/8"	Guidant Corporation 3200 Lakeside Dr. Santa Clara, CA 95052
UV-Cured Adhesive (20)	Urethane Oligomer (197-M) Acrylate	Dymax Corp. Torrington, CT
PET Shrink Tubing (26)	Polyethylene Terephthalate	Advanced Polymers, Inc. Salem, NH
Probe (12)	Fused Quartz	Polymicro Technologies, Inc. Phoenix, AZ
Optical Fiber Buffer (23)	Tefzel®	Spectran[1] Specialty Optic Co. Avon, CT
Optical Fiber Cladding (18)	Proprietary Flouropolymer Acrylate	Spectran[1] Specialty Optic Co. Avon, CT
Optical Fiber (11)	Fused Silica (Low OH^-)	Spectran[1] Specialty Optic Co. Avon, CT

The overall length of a channel forming device in accordance with the present invention is about 200 to about 400 cm with a typical value being about 350 cm. The actual length being determined by the location of the source of laser energy. The operative distal portion of the device, i.e. the portion which is inserted into the patient is about 10 to

about 60 cm in length. The probe tip for percutaneous use is about 3 to about 10 mm in length with the length of the exposed distal portion which extends out of the tubular support member being about 1 to about 5 mm, preferably about 2 to about 4 mm. For intraoperative use the probe tip should be about 5 to about 50 mm in length with about 2 to about 30 mm, preferably about 10 to about 25 mm, extending out of the tubular support member. The outer diameter of the probe tip is about 1 to about 3 mm, preferably about 1.5 to about 2 mm, and is measured at the widest portion of the bulbous tip which forms the lens. The outer diameter of the coating or jacket on the probe tip is essentially the same as the bulbous tip. The length of the outer tubular support member is about 0.3 to about 40 cm, preferably about 0.5 to about 30 cm and the length of the radial extension of the arms 15 is about 0.5 to about 2 mm.

Fig. 7 illustrates the use of the channel forming device wherein the probe tip 12 is disposed within the channel 34 in the ventricular wall 35. The arms 15 rest upon the ventricular surface 36 limiting the penetration of the probe tip 12.

An alternative embodiment is shown Figs. 8 - 11 which includes a channel forming device 110 which embodies features of the invention. The device 110 includes an elongated optical fiber 111, an elongated probe 112 disposed about and secured to the distal extremity of the optical fiber, and an outer tubular support member 113 secured to the exterior of the proximal extremity of the probe 112 and a distal portion of the optical fiber which is not disposed in the interior chamber 114 of the probe 112.

The exterior of the optical fiber 111 is provided with a fluoropolymeric cladding 115 along its length except for the distal portion 116 which extends into the distal portion of the interior chamber 114. The elongated probe 112 has a cylindrical body 117 which is

bonded to the optical fiber 111 by adhesive 118. The probe 112 has a bulbous distal end 119 which acts as a lens to control laser energy emitted from the distal end of the optical fiber to a location immediately distal to the lens to ensure formation a channel of a desired size. The cylindrical body 117 is provided with a coating or jacket 120 of suitable plastic material which will aid in the bonding of the outer tubular support member 113, strengthen the probe 112 and maintain the integrity of the probe, if the lens material fractures. Preferably, the plastic material is a heat shrinkable materials such as polyethylene terephthalate (PET) or polyethylene. The optical fiber 111 within the elongated probe 112 is provided with a body of adhesive 118 which prevents relative longitudinal movement between the optical fiber and the elongated probe 112. A fluoropolymer buffer 122 is disposed about the optical fiber 111 proximal to the body of adhesive 118 and extends proximally along essentially the remainder of the optical fiber. An outer jacket 123 is disposed about the fluoropolymer buffer 122 along its length, and terminates within the outer support tubular support member 113 proximal to the elongated probe 112. Filler tubing 124 is provided on the exterior of the buffer 122 and generally extends from the distal end of jacket 123 to the adhesive 118.

The outer tubular support member 113 has an outer and inner tubular elements 125 and 126 with the distal ends thereof forming a annular shoulder 127 which acts to limit the penetration of the probe 112 into the channel as it is being formed and thus the depth of the channel. The outer tubular element 122 is longer than the inner tubular element 126 and the proximal end of the outer tubular member is secured to the exterior of jacket 123. The inner tubular member 126 is secured to the filler shrink tubing 124 and the coating 120 on the cylindrical body 117 of the elongated probe 112. The inner and outer tubular elements 125 and 126 are preferably formed of heat shrinkable

materials such as polyethylene so that these elements can be heat shrunk onto the proximal extremity of the probe 111 and the distal extremity of the optical fiber which does not extend into the probe 112 and secure these members together. Other means of securing the outer tubular support member 113 to the optical fiber 111 and the elongated probe 112 may be employed, such as a suitable adhesive or insert injection molding.

The proximal end of the device 110 is provided with a connector 128 which has a rotatable, internally threaded collar 129 which facilitates an optical connection with a source of laser energy.

Although individual features of embodiments of the invention may be shown in some of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. Moreover, while the present invention has been described herein primarily in terms of a laser based channel forming device which is percutaneously introduced into the patient's vascular system and then advanced therein until the operative end is disposed within a chamber of the patient's heart, those skilled in the art will recognize that the device of the invention may be utilized in an interoperative procedure where the device is introduced into the patient's chest cavity and the channel is formed through the patient's epicardium. In this instance, however, the dimensions of the device may have to be changed to accommodate the slightly different delivery system. Additionally, a variety of non-laser channel forming devices may be utilized. See for example those non-laser devices described in co-pending application Serial No. 08/517,499, filed on August 9, 1995, which is incorporated herein in its entirety. Other modifications and improvements may be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A device for forming a channel into a wall of a patient's heart comprising:

a) an elongated shaft having a proximal shaft section and a distal shaft section;

b) means on the distal shaft section for forming a channel in a ventricular wall of a patient's heart; and

c) means to limit the depth of penetration of the means to form a channel into the ventricular wall during the formation of the channel therein.

2. The device of claim 1 wherein the means to limit the depth of penetration of the distal shaft section is a radial projection on the distal shaft section.

3. The device of claim 2 wherein the radial projection is an outwardly extending arm.

4. The device of claim 3 wherein the outwardly extending arm is foldable over the exterior of the distal shaft section to facilitate advancement of the device through an inner lumen of a delivery catheter.

5. A device for forming a channel into a wall of a patient's heart comprising:

a) an optical probe member having a distal end for controlling the shape of emitting laser radiation, a proximal end and an interior chamber;

b) an elongated optical fiber having proximal and distal ends, a distal extremity which extends through the proximal end of the probe member into the interior chamber thereof with the distal end of the optical fiber being in an optical transmitting relationship with the distal end of the optical probe member forming a lens; and

means to limit the depth of penetration of the optical probe member into tissue during the formation of the channel therein.

6. The device of claim 5 wherein a tubular support member is disposed about and secured to a proximal portion of the optical probe tip and a distal portion of the optical fiber which is not disposed within the interior chamber of the optical probe.

7. The device of claim 6 wherein the tubular support member has a distal end which acts as the radially extending surface to limit entry of the elongated probe member into the channel formed in the wall of the patient's heart.

8. The device of claim 6 wherein the elongated probe member is about 3 to about 10 mm in length.

9. The device of claim 6 wherein the elongated probe member is about 5 to about 50 mm in length.

10. The device of claim 6 wherein the length of the elongated probe member extending out of the encapsulating support member is about 1 to about 30 mm.

11. The device of claim 6 wherein the length of the elongated probe member extending out of the tubular support member is about 2 to about 25 mm.

12. The device of claim 6 wherein the optical fiber is provided with a fluoropolymer cladding over essentially its entire length excluding its distal tip which is essentially free of such cladding.

13. The device of claim 12 wherein a helical coil is disposed between the fluoropolymer cladding on the optical fiber and the proximal end of the outer tubular support member.

14. The device of claim 13 wherein the helical coil is provided with a polymer jacket to facilitate securing the outer tubular member to the optical fiber 11.

15. A device for forming a channel within a wall of a patient's heart comprising:

a) an optical probe member having a distal end forming a lens, a proximal end and an interior chamber;

b) an elongated optical fiber having proximal and distal ends, a distal extremity which extends through the proximal end of the probe member into the interior chamber thereof with the distal end of the optical fiber being in an optical transmitting relationship with the distal end of the optical probe member forming a lens;

c) an outer tubular support member having a distal extremity disposed about and secured to a proximal portion of the optical probe tip and a proximal extremity disposed about and

secured to a distal portion of the optical fiber which is not disposed within the interior chamber of the optical probe; and

d) a helical coil disposed between the proximal portion of the outer tubular support member and the distal portion of the optical fiber.

16. The device of claim 15 wherein at least the distal portion of the optical fiber is provided with a lubricous fluoropolymer coating.

17. The device of claim 15 wherein a polymer jacket is secured to the exterior of the helical coil.

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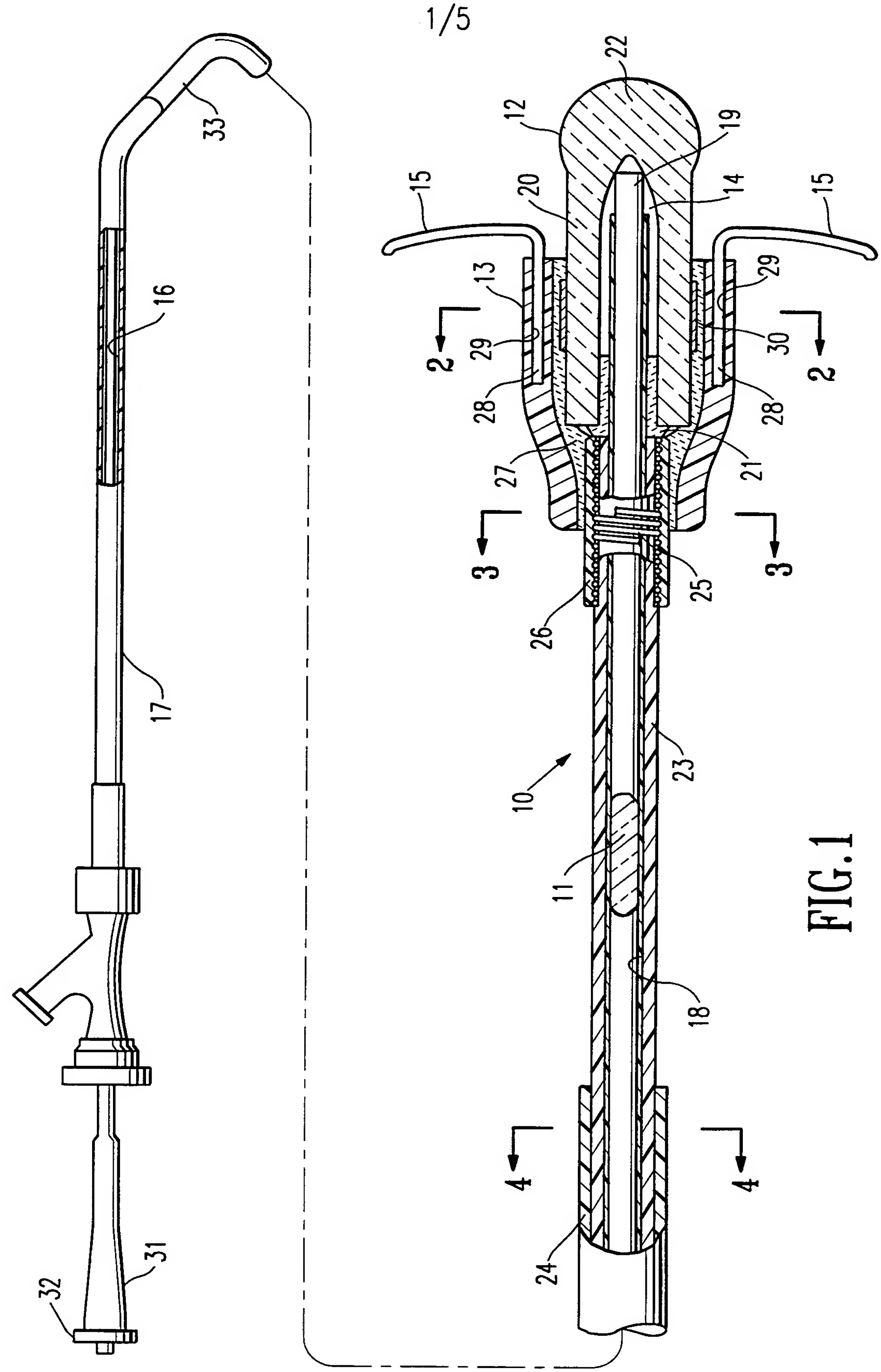
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FIG.1

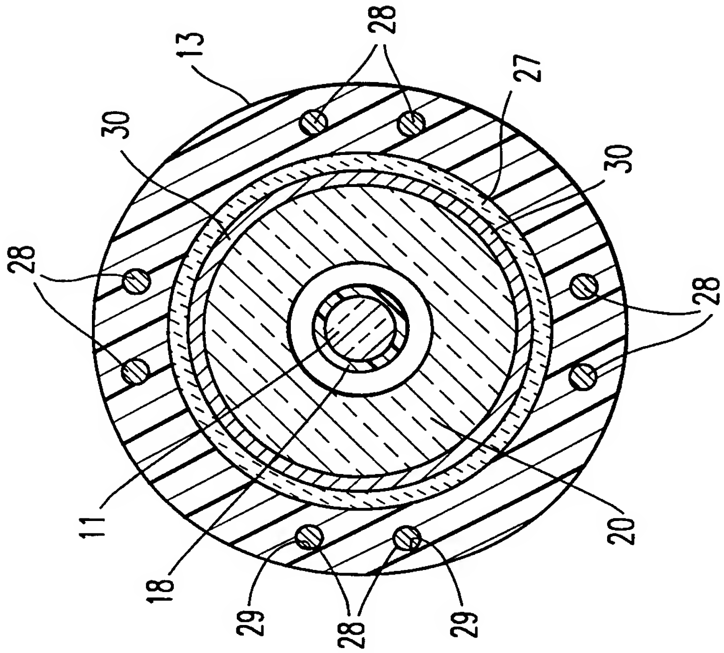

FIG. 2

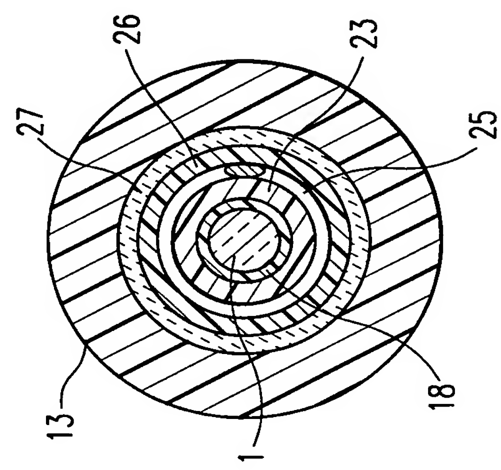

FIG. 3

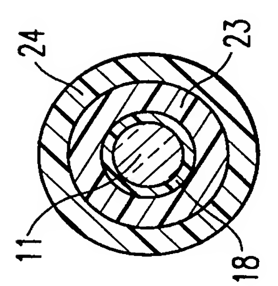

FIG. 4

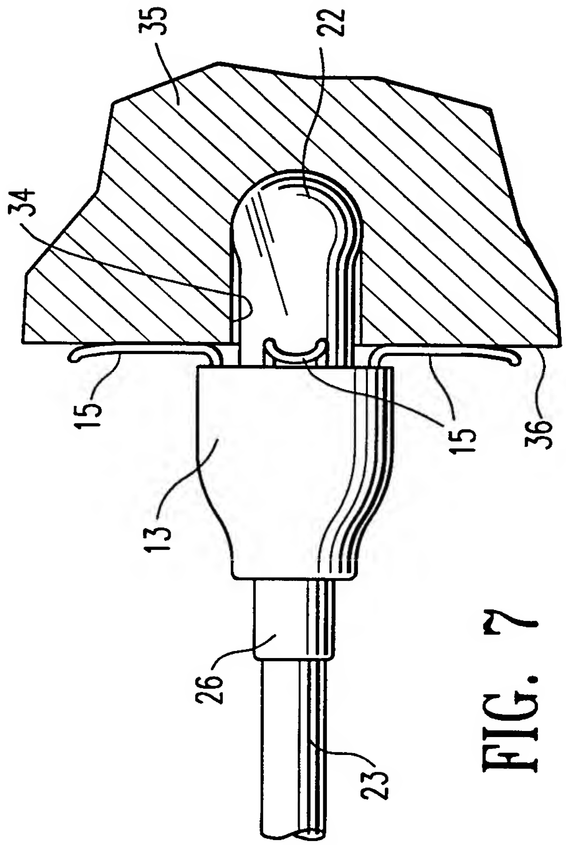

FIG. 7

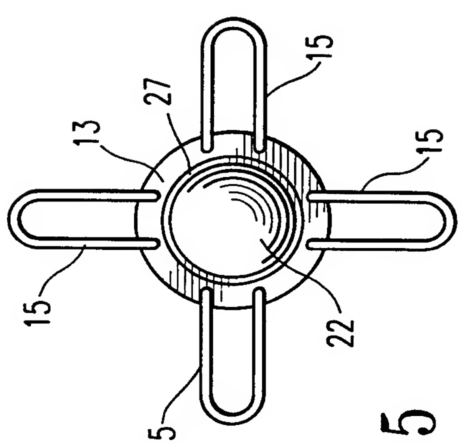

FIG. 5

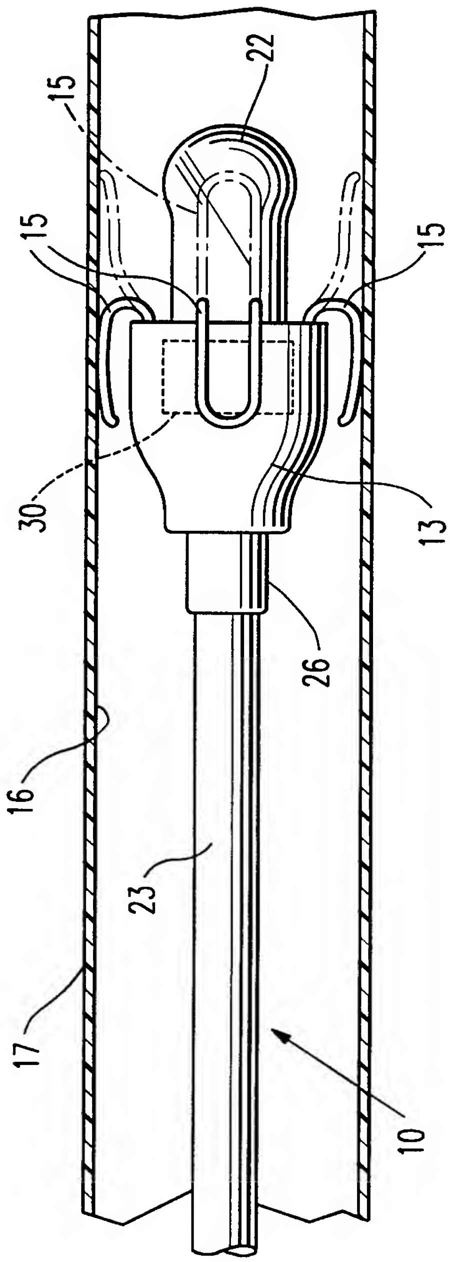

FIG. 6

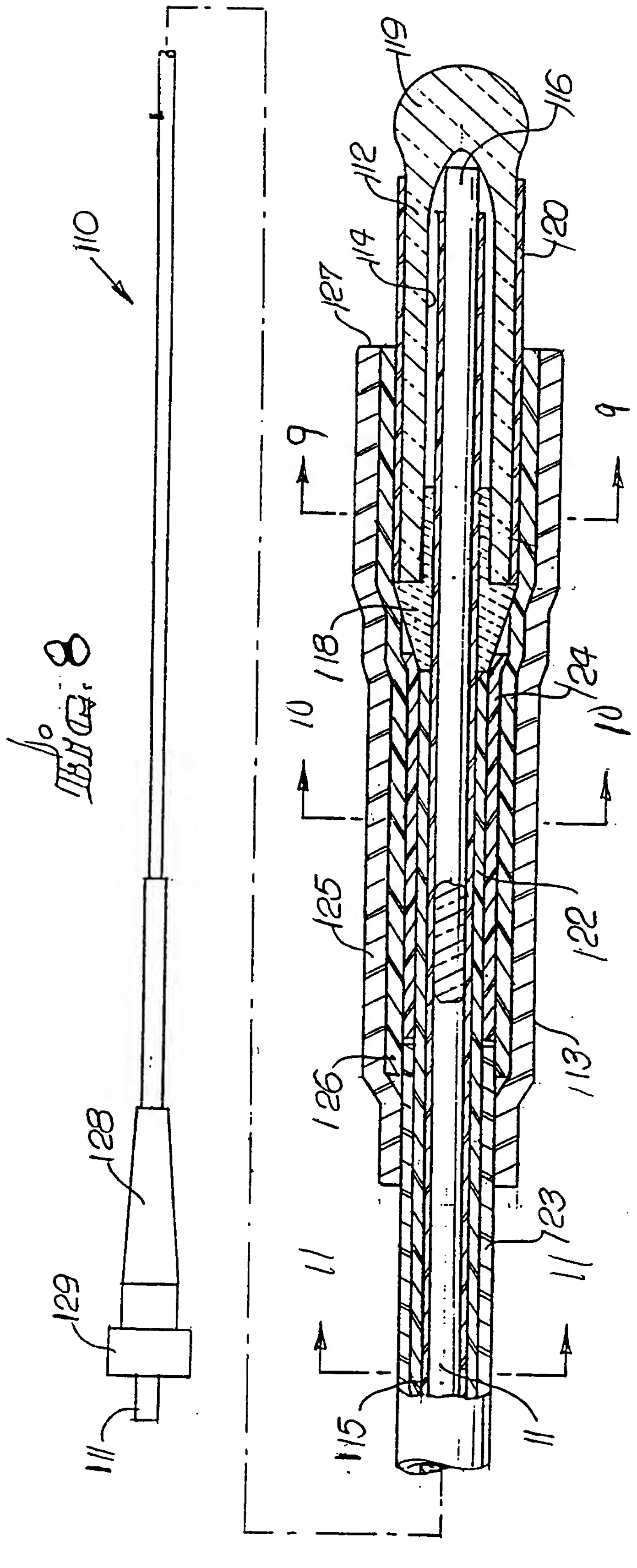
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FIG. 8

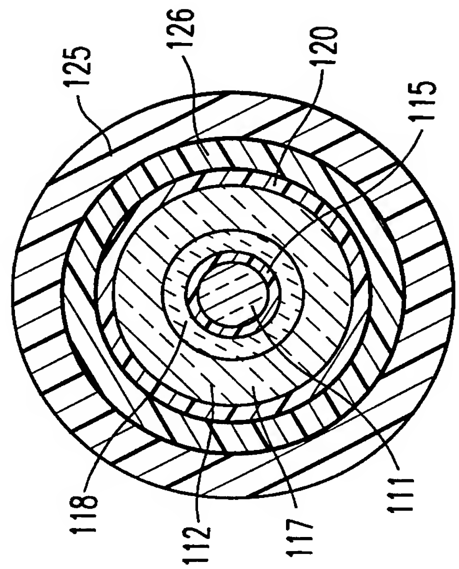

FIG. 9

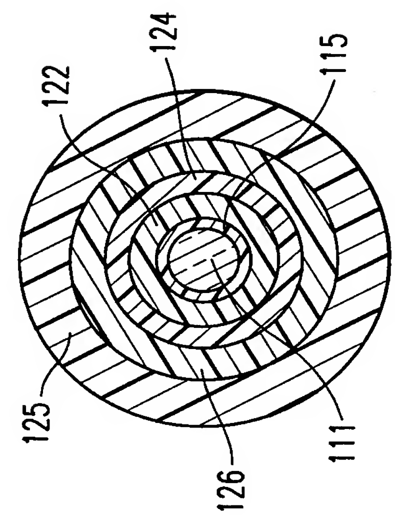

FIG. 10

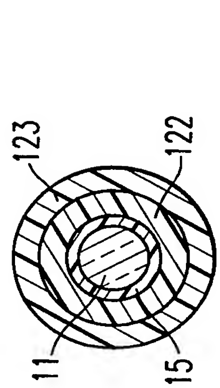

FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/09160

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 658 817 (HARDY) 21 April 1987 cited in the application see column 5, line 30-31; figure 3	1,2
Y	US,A,5 389 096 (AITA) 14 February 1995 cited in the application	1,2,5
A	see the whole document	15
Y	EP,A,0 292 621 (SLT) 30 November 1988 see column 7, paragraph 4; figures 2,5	1,2,5
A	DE,A,34 43 073 (NATH) 28 May 1986 see figure 3	6
A	US,A,4 660 571 (HESS) 28 April 1987 see column 6, paragraph 3-5; figure 7 see column 5, paragraph 4-5; figures 3,4	3

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
8 November 1996	13. 11. 96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Barton, S

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	GB,A,2 227 103 (MASAHIKO HOSHINO) 18 July 1990 see page 12, paragraph 2 ---	15
A	WO,A,94 20037 (AMERICAN MEDICAL) 15 September 1994 -----	

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INTERNATIONAL SEARCH REPORT

Inf ation on patent family members

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